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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MONSHIPOURI, MARYAM	

ART UNIT	PAPER NUMBER
1653	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/937,009	ALESSI ET AL.	
	Examiner	Art Unit	
	Maryam Monshipouri	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) *3,6-11,13-22 and 24-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,5,12 and 23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *filed 11/4/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicant's response to lack of unity requirement filed 5/9/2005 is acknowledged. Applicant elected Group I invention, claims 1, 4-5, 12 and 23 with traverse. Claims 3, 6-11, 13-22, 24-33 are withdrawn as drawn to non-elected invention.

In traversal of restriction requirement applicant argues the following: each of the claims relates to the unifying concept of substrate specificity of PDK1. In particular Group I includes claims which relate to altering the specificity of PDK1. Group II includes claims which relate to preparations alerting the specificity of PDK1. Group III includes claims which related to methods of identifying compounds which alter specificity of PDK1-2. Group VI, includes a claim which relates to a method of identifying compounds which are capable of mimicking the effect of compounds that affect PDK1, which has altered substrate specificity. Group V includes claims which relate to polypeptides which can be used to later the substrate specificity of PDK1. As such, applicant believes that he/she has contributed to a single special technical feature over the prior art and Groups I-V have unity of invention. Hence, for said reasons the lack of unity should be withdrawn.

These arguments were fully considered but were found **unpersuasive**. The examiner respectfully disagrees with the applicant that the unifying special technical features of all inventions of Groups I-V is substrate specificity of PDK1. This is because as indicated in the previous office action, according to criteria set forth under PCT Rule 13.1, the special technical feature of Groups I-V are identified to be :PDK1 substrates; PDK1 and derivatives thereof; modulators of PDK1; compounds which mimic the structure and properties of 3-phosphoinositides on PDK1-2 and methods of use thereof;

and PRK2, specific regions thereof, DNA sequences encoding said polypeptides, vectors and host cells comprising said DNA sequences, and methods of expressing said sequences, respectively.

Applicant is well aware that except for Group I which has PDK1 substrate and substrate specificity as its special technical feature, each and every of special technical features of inventions of Groups II-V are concepts and products other than substrates and substrate specificity of PDK1, rendering the claims subject to lack of unity of invention.

Therefore, due to reasons set forth above the examiner finds no reasons to withdraw lack of unity of invention. Hence, lack of unity requirement remains for the aforementioned reasons in addition to those provided in the previous office action and is hereby made **Final.**

DETAILED ACTION

Claims 1, 4-5 and 12, 23 are under examination on the merits. Claims 3, 6-11, 13-22, 24-33 are withdrawn as drawn to non-elected invention.

Claim Objections

Claims 1, 12 and 23 are objected to because of the following informalities: the terms "the" and "said" in claims 1, 12 and 23 appear to be redundant. Applicant is advised to delete one of said terms for clarity. Appropriate correction is required.

Claims 12 and 23 are objected to because of the following informalities: said claim depends from non-elected claims 11 and 22 respectively. Appropriate correction is required.

Claims 1, 4-5, 12 and 23 are objected to because of the following informalities: said claims appear to either define the PDK1 polypeptide numerous times, thereby creating confusion, or fail to define PRK2 at all. Applicant is advised to define each term, namely PDK1 and PRK2 once in the base claim and from then on use abbreviated terms for simplicity purposes. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is incomprehensible. The steps of the claim are unclear. Also it is unclear as to what the phrase "PDK1 derivable by a method of altering the substrate specificity of phosphoinositide-dependent kinase 1... " means. It is also unclear as to whether "interacting polypeptide" (see claim 1) and "substrate polypeptide" (claim 4) are the same polypeptides or not.

Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "identifiable by the method of claim 11" is unclear. Any compound may be "identifiable" by the method of claim 11. It is unclear as to what the metes and bounds of said phrase are.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4, 5, 12 and 23 are is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1, 4-5, 12 and 23 recite methods of using or making a **genera** of products which are merely defined by function.

The court of Appeals for the Federal Circuit has recently held that such a general definition does not meet the requirements of 35 U.S.C. 112, first paragraph. " A written description of an invention involving chemical genus, like a description of a chemical species, requires a precise definition, such as be structure, formula {or} chemical name, of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.,* 1997 U.S. App. LEXIS 18221, at *23, quoting *Fiers v. Revel,* 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). The court held that " in claims involving chemical materials, generic formulae usually indicate with specificity what generic claims encompass. One skilled in the art can distinguish such a formula fro others and can identify many of the species that the claims encompass. accordingly, such a formula is normally an adequate description of the claimed genus. In claims to genetic material, however, a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA,' without more, is not an adequate written description of the genus because it does not distinguish it from others. One skilled in the art therefore cannot, as one can do with a fully described genus visualize the identity of the members

of the genus". Here, applicant refers to phosphotinositide-dependent protein kinase 1 (PDK1) and PRK2, and PDK2 merely by function. It is not even clear if said products originate from humans and/or other mammalian species. The prior art does not indicate how much homology exists among all members of PDK1-2 or PRK2 across the species. Therefore such functional definition provides inadequate written description (i.e. structural information) for the genera as broadly claimed. Since said polypeptides are inadequately described methods of making or using said products (see claims 4, 5, 12 and 23) are also inadequately described.

With respect to "interacting polypeptide" (see claims 1, 4, 12 and 23) which comprises consensus sequences recited in claim 4, it should be reminded that such **genus** of interacting polypeptides is subject to written description for lack of sufficient structural information.

This is because a polypeptide (of for example 50,000 amino acids) which only needs to comprise basically 6-7 amino acids of a full-length polypeptide (i.e. PRK2) is totally incapable of retaining its appropriate three dimensional structure such that it can interact with PDK1 or its derivatives. Applicant is well aware that region A and region B of PRK2 as shown in figure 5, for example have many more amino acids than 6 amino acids indicted in the claims. Therefore, some additional structural information about the interacting polypeptide, in terms of what its other amino acid constituents may be, is necessary that is currently lacking in the specification.

Since the methods claims 1 and 4 lack adequate written description, their dependent claims 12 and 23 also lack written description.

Applicant is referred to the revised interim guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 1, 4, 12 and 13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of altering phosphorylation of human PDK1 of specific amino acid sequence with human PRK2 of specific amino acid sequence, does not reasonably provide enablement for methods of altering substrate specificity of PDK1 with an interacting polypeptide which comprises the amino acid sequence recited in claim 1 or methods of phosphorylating a residue of a substrate polypeptide as recited in claim 4, wherein the polypeptide comprises the amino acid sequence recited in claim 4, lines 5-6.

The criteria for undue experimentation, summarized in *re Wands*, 8, USPQ2n 1400 (Fed. Cir. 1988) are: 1) the quantity of experimentation necessary, 2) the amount of direction or guidance presented, 3) the presence and absence of working examples, 4) the nature of the invention, 5) the state of prior art, 6) the relative skill of those in the art, 7) the predictability or unpredictability of the art, and 8) the breadth of the claims.

Claim 1 and 4 are directed to methods of use of "interacting polypeptides" or "substrate polypeptides" comprising an amino acid sequence as recited in either claims 1 and/or 4, wherein said polypeptides are not enabled. This is because a polypeptide (of for example 50,000 amino acids) which only needs to comprise basically 6-7 amino acids of a full-length polypeptide (i.e. PRK2) is totally incapable of retaining its appropriate three dimensional structure such that it can interact with PDK1 or its

derivatives. However, the disclosure fails to teach which residues within the claimed interacting or sustrate polypeptides must be rateined such said "substrate" or "interacting polypeptides" retain the ability to bind PDK1 and be phosphorylated by said protein. No examples of such residues are provided either. Current state of prior art indicates that once two-three residues of a full-length polypeptide is simultaneously mutated said polypeptide does not necessarily retain the binding or activation properties of said full-length polypeptide. Therefore due to lack of sufficient guidance and examples provided in the disclosure and due to unpredictability of prior art as to which residues within claimed interacting or substrate polypeptides is in charge of binding and being activated by PDK1 one of skill in the art has to go through the burden of undue experimentation in order to screen to those interacting or substrate polypeptides that are within the scope of this invention and as such claims 1, 4 and 12 and 23 go beyond the scope of the disclosure.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maryam Monshipouri whose telephone number is (571) 272-0932. The examiner can normally be reached on 7:00 a.m to 4:30 p.m. except for alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weber Jon P. can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

M. Monshi

Maryam Monshipouri Ph.D.

Primary Examiner

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